

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

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PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Date of mailing
(day/month/year) **25 JUL 2005**

Applicant's or agent's file reference

FOR FURTHER ACTION

See paragraph 2 below

2004367-0045

International application No.

International filing date (day/month/year)

Priority date (day/month/year)

PCT/US04/43999

31 December 2004 (31.12.2004)

31 December 2003 (31.12.2003)

International Patent Classification (IPC) or both national classification and IPC

IPC(7): A61K 35/32 and US Cl.: 424/549/549, 429; 514/12; 435/1.1; 623/16.11, 23.61

Applicant

OSTEOTECH, INC.

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/ US

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**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International Application No.

PCT/US04/43999

Box No. I Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This opinion has been established on the basis of a translation from the original language into the following language _____, which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).

2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

☐ a sequence listing

☐ table(s) related to the sequence listing

b. format of material

☐ in written format

☐ in computer readable form

c. time of filing/furnishing

☐ contained in international application as filed.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

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**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/US04/43999

Box No. V Reasoned statement under Rule 43 bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims <u>18,19,29-51,55,57,59,62-65,69 and 71</u>	YES
	Claims <u>1-17,20-28,52-54,56,58,60,61,66-68,70 and 72</u>	NO
Inventive step (IS)	Claims <u>NONE</u>	YES
	Claims <u>1-72</u>	NO
Industrial applicability (IA)	Claims <u>1-72</u>	YES
	Claims <u>NONE</u>	NO

2. Citations and explanations:

Claims 1-17, 20-28, 52-53, 54, 58, 60-61, 66-68, 70 & 72 lack novelty under PCT Article 33(2) as being anticipated by O'Leary.

O'Leary teaches a human demineralized bone material which is to be combined with any of a variety of substances including collagenase, peptidases and other enzymes and other therapeutic substances. The claimed cells and tissue are also not novel as they represent any known cells or tissue- the exposure to the DBM not producing novel cells or tissues. The reference anticipates the claim subject matter as the biologic activity claimed would be inherent to the material of the reference.

Claims 1-17, 20-23, 54, 56, 66, 70 & 72 lack novelty under PCT Article 33(2) as being anticipated by Qvist.

Qvist teaches a demineralized bone material modified by collagenase. The reference anticipates the claim subject matter as the biologic activity claimed would be inherent to the material of the reference.

Claims 1-17, 20-23, 54, 56, 66, 70 & 72 lack novelty under PCT Article 33(2) as being anticipated by Wallace.

Wallace teaches a demineralized bone material modified by trypsin. The reference anticipates the claim subject matter as the biologic activity claimed would be inherent to the material of the reference.

Claim 1-72 lack an inventive step under PCT Article 33(3) as being obvious over O'Leary taken with Qvist and Wallace.

The references don't teach all of applicant's claimed embodiments however it would have been obvious to a routineer in the art to optimize the materials and methods of the references because the references disclose the composition of DBM, the bioactivity thereof and disclose modifying or supplementing the activity by treating the material with enzymes (particularly hydrolytic enzymes) and adding bioactive compounds to the material. The desired properties of DBM are known and the means and methods for optimizing it, i.e. modifying or inhibiting the contained bioactive factors by any known means, are known so the claimed invention would've been at least suggested to a routineer in the art.

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